REMARKS/ARGUMENTS

Applicant has cancelled Claims 1, 7, and 10, and has amended Claims 2, 8, 11-12, 16-17, 29, and 34-46, and has preserved Claims 3-6, 9, 13-15, 18-28, and 30-33 in either their "Original" or "Previously Presented" form preceding in the record prior to this amendment and response.

Claims 2 (amended into independent form), 12 (amended into independent form), 44, 45, and 46, all herein amended, are all of the independent claims which remain in the Application.

Ample support for the present amendments, and remarks made hereunder, is provided throughout the specification, including without limitation at the following locations (in addition to those other locations also indicated elsewhere in these remarks): in the Specification at [0026], [0028], [0043], [0049], [0070]-[0071], [0078]-[0079], [0095]-[0096], [0098], [00103], [00111]-[00112], [00134]-[00143], [00144], [00154-[00156]; Figs. 1-2 and 5-7; originally filed Claims; and Abstract. No new matter is added by this amendment.

Rejections under 35 USC 102

Claims 1-10, 12, 14, 15, 17-19, 29, 30, 34-37, 39, 43, and 44 are rejected under 35 USC § 102(e) as being anticipated by O'Brien et al. (US 2005/0060021)("O'Brien").

Applicant has herein amended Claim 2, which is now rewritten in independent form, and which now incorporates the previously pending subject matter of each of Claims 1 and 7 (now cancelled), in addition to other language also added to the claim.

Applicant has also herein amended Claim 12 to now be presented in independent form by merely incorporating the previously pending subject matter of Claim 1 (now cancelled).

Originally independent Claims 2 and 44 (and certain dependent claims related thereto) are addressed in their currently amended form in succession below;

whereas remarks addressing Claim 12, now amended as rewritten from originally dependent to now independent form, (and its dependent claims) are provided thereafter.

Independent Claim 2, as Amended

Amended Claim 2 now requires, in combination with an endolumenal stent with a porous surface comprising a first material and having a plurality of pores:

(a) a second composite material that is different than the first material and that comprises a plurality of discrete particles comprising a bioerodible material in combination with a bioactive agent; and

(b) the plurality of discrete particles are structurally co-deposited together with said first material on said endolumenal surface and within each of the pores that are formed at least in part around the particles and thereby comprising a co-deposited composite surface coating, such that the pores having an inner diameter in the vicinity of the particles that is substantially equivalent to an outer diameter of the particles.

A party asserting that a patent claim is anticipated under 35 USC 102 must demonstrate among other things, "identity of invention." *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). For a prior art reference to anticipate in terms of 35 USC 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, (Fed. Cir. 1990).

O'Brien et al. do not show each and every element of the rejected claims as presently amended, namely claim 2 and all claims which depend on claim 2. O'Brien et al. therefore do not anticipate these claims.

The Office Action alleged that O'Brien discloses a stent comprising a scaffold from a third material, an intermediate fourth material, a porous surface comprising a first coating material having a plurality of discrete pores and a second composite material comprising a plurality of particles located within each of the pores and composed of a bioactive agent in combination with a bioerodable polymer material.

Contrary to the allegation in the Office Action that a plurality of particles is disclosed in O'Brien, Applicant cannot find such a disclosure anywhere in O'Brien et

al. **O'Brien does not disclose a plurality of discrete particles, much less particles constructed of composite material comprising bioerodible polymer in combination with a bioactive agent, much less such composite particles in a structurally co-deposited composite surface coating.**

The Office Action's reference to ¶36 of O'Brien et al. to allegedly show the teaching of particles is improper because Figure 2C of O'Brien et al. does not show particles but is a view from the top or bottom of a tubular element. The diameters indicated refer to the diameter of the tube and not to any particle. O'Brien states at that "...a therapeutic agent in the reservoir can be combined in a matrix of erodible polymer" (O'Brien at [0034]) and that "The therapeutic agent provided in the volumes and voids of the porous layer can be dissolved in a carrier, such as an erodible polymer or a diffusion-controlling polymer." (O'Brien at [0060]) However, this does not describe or suggest providing such a matrix as discrete composite particles, much less such discrete particles deposited in some way within a porous coating. To disclose a "matrix" does not disclose or suggest a plurality of discrete particles. That a volume of a matrix may be defined by an inner diameter of a reservoir where it sits does not convert the matrix necessarily into a particle, much less a plurality of particles.

Applicant refers to Fig. 2 of the present disclosure, specifically to item **40** which shows a schematic example of discrete particles housed in a porous coating which are illustrative of the novel structure now presently claimed in claim 2, and which is not found in O'Brien's disclosure.

Even, arguendo, if O'Brien were found to disclose composite bioerodible material/bioactive agent particles, which Applicant asserts it does not, it nonetheless still does not anticipate, suggest, or otherwise render obvious a structurally co-deposited composite surface coating of discrete particles co-deposited within a coating material having its porosity formed around the particles. Such further clarifying limitations are now required by Claim 2 as currently amendment, and not described, suggested, or otherwise rendered obvious by O'Brien.

In addition to failing to disclose or anticipate any incorporation of a plurality of discrete composite bioerodible/bioactive particles into a stent coating, it also would not

be apparent to one of ordinary skill how such particles could be introduced to such pre-formed pores of O'Brien's disclosed coating. O'Brien only describes providing its "matrix" to its stent after forming its porous coating layer. For example, O'Brien states:

> "Referring to FIG. 4D, a material such as a therapeutic agent can be provided into the porous structure by, for example, dipping, spray coating or the like. The therapeutic agent can be provided into the volumes and void regions defined by the post-shaped elements. In FIG. 4D, a therapeutic agent 74 has been **delivered into** both the internal volumes of the post-shaped elements 70 and the void regions 72." (O'Brien at [0048]; see also at [0034])(emphasis added).

O'Brien does not disclose, teach, or suggest any way that discrete particles could be deposited within the pre-formed pores described for the coating of O'Brien's disclosure, nor would it be apparent to one of ordinary skill how to do this based upon review of O'Brien's disclosure. O'Brien also does not disclose, teach, or suggest: any form of particulate (or "matrix" for that matter) that is, or should or could be, "co-deposited" with a coating material within a porous, structurally co-deposited composite coating layer. If anything, O'Brien teaches away from such anticipation. Accordingly, based upon the O'Brien disclosure one of ordinary skill would not expect the beneficial result presented by the structurally co-deposited composite coating layer required as a necessary limitation in Applicant's amended Claim 2.

Claim 2's Dependent Claims

Applicant further notes that various additional claims that depend from independent claim 2 remain in the present application. These dependent claims are either preserved in their original form or are also hereby amended to clarify certain aspects captured by the particular claim(s). These claims variously provide further distinguishing features over the presently known art, including the O'Brien et al. disclosure cited in the present rejection. This is in particular the case with respect to the overall combinations of features claimed through dependency, which incorporate by reference the distinguishing features of claim 2 as noted above.

In addition, however, the further features and aspects noted in these dependent claims also provide additional separation from the disclosed art that Applicant submits

are sufficient to render such claims allowable over and above the basis from respectively incorporated claim 2. While the Office Action did not address detailed bases for rejecting these dependent claims by name in the detailed explanation, Applicant attempts below to address certain dependent claims in view of O'Brien, and to respond where certain statements made in the detailed explanation appear to have been directed toward certain particular claims.

In one regard, the Office Action stated that the O'Brien "pores comprise an inner diameter less than 1 micron (para.0036). The particle diameter may be defined as the inner diameter of the pore, and thus the particle diameter is less than 1 micron." It was not made clear how this allegation relates to any specific claim rejection, but Applicant assumes that it relates at least to claims 5 and 10, which required that the claimed particles be less than about 1 micron.

While Claim 10 has since been cancelled hereunder (as redundant per amendment to antecedent claims), Claim 5 is preserved in its previously presented form. Applicant has provided remarks above traversing the allegation in the Office Action that O'Brien discloses discrete particles as Applicant has claimed, and such remarks are further incorporated here again by reference with respect to Claim 5, and furthermore with respect to dependent claims 3 and 4 which also remain pending.

Dependent Claims 8 and 9 have also been amended hereunder to now require, in addition to various different upper limits already provided in the claims, that the composite particles required in the structurally co-deposited composite surface coating of Claim 2 also be "greater than about 1 micron." The Office Action admitted that "the particle diameter (of O'Brien) is less than 1 micron" (parenthetical added). O'Brien's Figure 2C, recited in the Office Action, depicts a view from the top or bottom of a tubular element. The diameter refers to the diameter of the tube and not to any particle. The diameter is also indicated to be less than 1 micron in O'Brien et al. O'Brien discloses diameter ranges of "about 20nm to about 200 nm," "5 nm to about 200 nm (e.g., about 70 nm to about 100 nm)," and "about 70 nm to about 100 nm." (O'Brien at [0014], [0036], and [0080]). While Applicant reiterates its traversal that there are no O'Brien particles at all, regardless of size, as claimed by Applicant, Applicant asserts that this admission nonetheless tacitly admits that even if such particles were found they do not

meet the "greater than about 1 micron" limitation in these Claims 8 and 9, as currently amended, and thus they are not anticipated by O'Brien.

Claim 17 as presently amended provides still further distinguishing required features over O'Brien in addition to those found in the base claim 2. More specifically, amended Claim 17 requires that the endolumenal stent comprises a scaffold constructed from a third material, and that the first material with the pores comprises a coating located on and in contact with the third material. This is not disclosed or suggested by O'Brien, which only features an intermediate layer from which the anodized porous layer is grown and that is located between the porous layer and the stent scaffold substrate. More specifically, O'Brien discloses only anodization to grow a porous coating onto a substrate surface from an anodizable surface layer (see for example FIGS. 2A-B and 4A-B, and [0040]-[0047]). Accordingly, Applicants assert O'Brien does not anticipate Claim 17.

Independent Claim 44, as Amended

Independent claim 44 already required "...a plurality of composite particles" prior to this amendment and response, which limitation is of course preserved (and in fact now further developed) in the present amendments made to these claims. O'Brien et al. do not teach this element of claims 44-46 and therefore do not anticipate the claim on this basis alone. In addition, further aspects of these claims, including before and as presently amended, are also not disclosed, suggested, or otherwise rendered obvious by O'Brien.

In particular, Claim 44 has been herein amended to now require, in addition to other aspects of an an endolumenal stent with a substrate having an outer surface, a coating material coupled to the outer surface, and a plurality of composite particles within the coating material that comprise bioerodible material in combination with a bioactive agent:

(1) the plurality of composite particles are structurally co-deposited within the coating material on the outer surface to thereby comprise a structurally co-deposited composite surface coating on the outer surface with the coating material formed at least in part around the composite particles; and

(2) the plurality of composite particles are adapted to release the bioactive agent and the bioerodable material is adapted to erode from the coating material to thereby leave a plurality of voids in the remaining coating material when the endolumenal stent is implanted within a body of a patient.

As noted above with respect to amended Claim 2, these features required by Claim 44 are also not disclosed in O'Brien, nor are they suggested in any way by O'Brien, nor would they represent an expected beneficial result to one of ordinary skill based upon review of O'Brien's disclosure. O'Brien does not disclose or suggest a plurality of discrete composite bioerodible polymer/bioactive agent particles, much less incorporated within a surface coating material, much less within a structurally co-deposited composite surface coating with a coating material formed around the particles. In addition to the specific arguments set forth here with respect to Claim 44 in particular, additional remarks noted above with respect to Claim 2 are also incorporated by reference here with respect to Claim 44 as would be appropriate and apparent to one of ordinary skill.

Independent Claim 12, as Amended (From Dependent into Independent Form)

Claim 12 has been rewritten into independent form, merely by incorporating the subject matter of claim 1 (now cancelled). This claim requires, among other limitations addressing an endolumenal stent system with a porous surface comprising a first material with a plurality of pores, and a second composite material that is different than the first material and that is located within each of the pores and comprising a bioerodable material in combination with a bioactive agent:

(1) the first material of the porous surface not inherently porous; and

(2) the pores are formed at discrete locations within the first material along the surface.

It is not clear in the explanation portion of the Office Action for this ground for rejection where or how O'Brien was intended to be applied against Claim 12, as while it was included summarily under the ground for rejection it was not addressed directly in

the body of the section, nor were its required limitations directly addressed or compared against allegedly anticipatory disclosure in O'Brien.

However, the Office Action did state as to this general ground for rejecting the subject claims on the whole that O'Brien's "pores are formed in the first coating material through an anodization process."([0041]). It is believed, though without certainty, that, since no claim of Applicant's included the term anodization, the Office Action may have intended this statement to be applied to Claim 12. Furthermore, the Office Action stated in explaining another ground of rejection under the Office Action that "O'Brien et al. do not disclose the first material ... is inherently porous."

It is believed, per these two statements in the Office Action, that the Examiner interprets O'Brien's anodization process as one whereby pores are "formed in the first coating" that is not otherwise "inherently porous." However, anodization as used by O'Brien grows a porous coating onto a substrate surface from an anodizable surface layer (see for example FIGS. 2A-B and 4A-B, and [0040]-[0047]). Merriam's Webster's on-line dictionary also defines "anodize" to mean "to subject (a metal) to electrolytic action as the anode of a cell in order to coat with a ... film."

Accordingly, O'Brien's disclosure does not anticipate Applicant's claim 12, either prior to or as currently amended in its independent form.

The Office Action further included Claims 14 and 15 under this ground for rejection based upon anticipation by O'Brien. These Claims require that the plurality of pores be "photochemically etched" (Claim 14) or "chemically etched" (Claim 15) into the first material. O'Brien makes no such disclosure, nor does it suggest these processes or resulting structures as desired alternatives to its porous anodization process and structure disclosed.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the Office's rejection of claims 1-10, 12, 14, 15, 17-19, 29, 30, 34-37, 39, 43, and 44 under 35 USC § 102.

35 U.S.C. § 103 Rejections

Claims 11, 13, and 16 are rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claims 1 and 12, in view of Lye et al. (US 2004/0148015).

Regarding claims 11 and 16, the Office Action alleged that although O'Brien et al. do not disclose that the first material is sintered or is inherently porous, Lye et al. disclose a similar device including a stent with a porous surface and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the first material included an inherently porous material, such as a sintered material, to simplify the manufacturing process by eliminating the step of forming the pores by anodization.

Applicant submits that O'Brien et al. in view of Lye et al. do not teach or suggest the elements of presently amended independent claim 2 and its dependent claims. More specifically, the combination of O'Brien et al. and Lye et al. do not teach or suggest the second composite material of the present endolumenal stent system comprising a plurality of particles, much less such particles formed of composite combination bioerodible/bioactive materials, much less such composite particles in a structurally co-deposited composite surface coating.

Furthermore, O'Brien's disclosure is centered around anodized coatings. Its disclosure is largely dedicated toward harnessing and advancing various alleged, perceived benefits of that particular approach, such as colors etc. associated with different degrees of anodization, and other structural aspects alleged to be particularly unique to its anodized process and result. To modify O'Brien's coating to a different coating instead of anodization is to obviate the principal direction and purpose of the disclosure. O'Brien teaches away from dropping anodization in favor of another coating approach (where anodized coatings are disclosed).

Furthermore, Applicant further asserts that neither of the O'Brien anodization or the Lyet et al. reference relied upon for an alternative sintering approach discloses or renders obvious a co-deposited composite surface coating as required by Applicant's claim.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 11, 13, and 16 under 35 USC § 103.

Claims 20-28, 31-33, 45, and 46 are rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US2005/0060021)("O'Brien"), as applied to claim 19, in view of Gertner et al. (US 2003/0060873)("Gertner").

While this instant ground for rejection is premised upon application of O'Brien over these subject claims "as applied to claim 19 above," the rejection of claim 19 cross-referenced in the Office Action was only summarily addressed in that overall statement of this other ground for rejection, and no detailed basis for rejecting that specific claim or its combination of elements in context of O'Brien was provided. However, it is clear that this instant ground for rejection was premised at least in part upon the repeat allegation in the Office Action that O'Brien discloses the same plurality of particles that Applicant requires in these claims. Applicant again traverses this allegation, incorporating by reference here again those related remarks above addressing this matter with respect to independent Claim 2, as currently amended, as appropriately also applied with respect to these claims.

The Office Action alleged that although O'Brien et al. do not disclose that the electrochemically deposited material is an electrolessly electrochemically deposited material including a composite with a metal and a reducing agent of that metal, Gertner et al. disclose a similar device including a stent comprising a scaffold, a porous surface on the stent comprising a first material and a plurality of pores and a second material comprising a bioactive agent located within the pores using an alternate first material. Applicant traverses this ground for rejection, in context of the subject claims as affected by the current amendment, below.

Claims 20-28, 45, and 46

In regards to Claims 20-28, these claims depend variously from independent Claim 2, as currently amended, which Applicant argues hereunder should be considered patentable and allowed. Accordingly, these Applicant respectfully asserts that this ground for rejection should be reconsidered and withdrawn, and that these dependent claims should be allowed on this basis alone. Further to the extent that these particular claims have been further rejected on the basis of certain aspects of further limitations in these claims related to electrolessly electrochemically co-deposited surface coatings in context of further application of Gertner's disclosure of electroless

deposition, Applicant addresses this alleged reference combination in context of the present rejection below. Arguments presented below with respect to independent claims 45 and 46 are incorporated here similarly with respect to these dependent claims as would be appropriate and understood by one of ordinary skill.

The Office Action stated with respect to rejecting these claims over this combination of references that: "O'Brien et al. disclose the pores are formed in the first coating material through an anodization process. ([0041]) However, O'Brien et al. do not disclose the electrochemically deposited material is an electrolessly electrochemically deposited material include a composite with a metal and a reducing agent of that metal." It goes on to reference Gertner for providing an electroless electrochemical process which is used to modify O'Brien to allegedly surplant its anodization process and thus arrive at Applicant's claimed invention.

Claim 45, as currently amended, requires, in addition to other aspects of a system for depositing a bioactive coating onto a surface of an endolumenal stent:

(1) a plurality of metal ions within a coating environment that also includes a plurality of composite particles that each comprises a composite material that comprises a bioactive agent in combination with a bioerodable carrier material; and

(2) the coating environment is adapted to co-deposit the metal from the metal ions into a coating material in combination with the composite particles onto the endolumenal stent surface to form a structurally co-deposited composite surface coating when the endolumenal stent is exposed to the coating environment.

As noted above with respect to amended Claims 2 and 44, neither the discrete composite particles featured, nor the structurally co-deposited composite surface coating provided by, the system of this Claim 45 are disclosed in O'Brien, nor are they suggested in any way by O'Brien, nor would they represent an expected beneficial result to one of ordinary skill based upon review of O'Brien's disclosure. Nor are these provided, nor would the result by expectation, by Gertner. O'Brien does not disclose or suggest a plurality of discrete composite bioerodible polymer/bioactive agent particles, much less incorporated within a surface coating material, much less structurally co-deposited within a composite coating layer with a coating material conformed at least in

part to the particles. Gertner also does not disclose or suggest as obvious such composite particles, or their incorporation into electroless electrochemical baths or coatings, nor does either reference teach how such might be accomplished or perceived benefits of doing such.

O'Brien also does not alone disclose, suggest, or otherwise render obvious providing a system for depositing a surface coating on a stent that includes a coating environment that incorporates such particles in combination with metal ions, and that is adapted to co-deposit metal from those metal ions into a coating material that is structurally co-deposited with the composite particles. O'Brien only describes providing its "matrix" to its stent after forming its porous coating layer. For example, O'Brien states:

> "Referring to FIG. 4D, a material such as a therapeutic agent can be provided into the porous structure by, for example, dipping, spray coating or the like. The therapeutic agent can be provided into the volumes and void regions defined by the post-shaped elements. In FIG. 4D, a therapeutic agent 74 has been **delivered into** both the internal volumes of the post-shaped elements 70 and the void regions 72." (O'Brien at [0048]; see also at [0034])(emphasis added).

Accordingly, by modifying O'Brien as alleged in the Office Action to surplant its anodization with Gertner's electroless electrochemical deposition process, the O'Brien reference has to be modified to change the coating material used, and to change the process from post-loading pores to co-deposition. Even if this were an appropriate series of modifications, which Applicant asserts it is not, the composite particles co-deposited per Applicant's claims are still not found. O'Brien was alleged in the Office Action to be the reference disclosing such composite particulate by virtue of the mere existence of a composite "matrix" deposited within pre-formed pores. But if O'Brien were to be modified as alleged to now seek co-deposition, the alleged source of composite particulate would be lost.

O'Brien also does not disclose, teach, or suggest: any form of particulate (or "matrix" for that matter) that is, or should or could be, "co-deposited" with a coating material within a porous, structurally co-deposited composite coating layer. O'Brien further fails to disclose, suggest, or otherwise render obvious a coating environment incorporating those components or configured for such co-deposition as required by

Claim 45. If anything, O'Brien teaches away from such a result. Accordingly, based upon the O'Brien disclosure one of ordinary skill would not expect the beneficial result presented by a coating environment required by Applicant's amended Claim 45, either prior to or in its currently amended form. Gertner, while disclosing electroless electrochemical co-deposition of bioactive particulate, failed to disclose or suggest the significant benefits, which Applicant has first recognized, of providing bioactive agents in composite particulate form, in combination with a bioerodible material, that is capable of co-depositing into a coating. Applicant's different system and approach produces a different and improved coating environment for co-deposition, and a different and improved coating result (such as for example regarding elution properties). Moreover, one of ordinary skill in the art would not seek to modify O'Brien in view of Gertner, or Gertner in view of O'Brien, in a way that has been done in the Office Action – the alleged modifications depart from the direction of the teachings in the references.

Claim 46 also requires, in addition to other limitations drawn to a system for depositing a bioactive coating onto a surface of an endolumenal stent:

(1) a coating environment with a coating precursor material and a plurality of composite particles located within the coating environment and that comprise a composite material that comprises a bioerodable material in combination with a bioactive agent; and

(2) the coating environment is adapted to co-deposit a coating material from the precursor material in combination with the composite particles onto the surface so as to form a structurally co-deposited composite surface coating that is adapted to release the bioactive agent and erode the bioerodable material from the coating material that remains on the surface when the coated surface is exposed to a body of a patient.

The remarks above addressing the rejection of Claim 45 apply similarly and are incorporated again by reference here with respect to Claim 46 as appropriate and would be understood by one of ordinary skill.

Further to this ground for rejecting the claims as addressed above, The Office Action alleged theories as to why it would be obvious to modify the device of O'Brien such that its first "porous" coating material was composed of electrolessly deposited material. In advancing these theories, benefits of electroless electrochemical

deposition put forth by Gertner were proffered to present improved benefits to O'Brien as modified by replacing its anodization method and resulting structure with that electroless electrochemical deposition. However, neither of these still disclose or contemplate any incorporation of composite particles of the type claimed by Applicant, much less in such a modified co-deposition process either required by Applicant it its claims or as theorized in the alleged combination between these references and theorized results that could result.

Moreover, while the Office Action alleged perceived benefits to modifying O'Brien via Gertner, its actually Applicant's invention that presents significant new benefits over both Gertner, and O'Brien, and even their alleged combination (if it were to be considered by one of ordinary skill) – which do not result in any expectation of Applicant's claimed invention. As Applicant stated in its application:

> "Such drug-carrying particulate co-deposition may be beneficially particles formed of principally only the drug itself. However, depending upon the particular drug and particular electroless electrochemical bath employed for co-deposition, such particles may not maintain integrity during the coating process, or may dissolve, degrading the benefits of providing the particulates within the bath in the first place to enhance co-deposition. Moreover, co-deposition of solely drug particulates within an electrolessly electrochemically formed nano-porous composite matrix is generally expected to elute according to a diffusion gradient profile. There would be additional benefit therefore if such particulate additive were complexed in a composite of drug and another structural material, such as in particular a bioerodible material that suitably maintains the particulate integrity through the co-deposition process and provides suitable elution characteristics in vivo." (Applicant's originally files Application at [0028]).

While the Office Action recognized the significant benefits provided by the unique approach taken by Gertner relative to O'Brien with respect to various particular advantages of electroless electrochemical deposition, and co-deposition of drugs into device coatings, the present Applicant has nonetheless invented a substantial improvement to that baseline approach. Applicant's incorporation of composite micro- and/or nano- composite bioerodible/bioactive particles into a structurally co-deposited surface coating, and/or into a coating environment suitable to provide such structure (e.g. electroless electrochemical) is a clearly unanticipated and unsuggested

improvement in context of Gertner, O'Brien, or their alleged combination. A different coating environment is created than expected from Gertner (e.g. protecting drug from the environment via the bioerodible portion), and a different composite coating result is created than expected from Gertner (e.g. more efficient, and diverse, capability of managing and/or varying elution profiles). One of ordinary skill in the art would not arrive at Applicant's invention based upon review of either or both of these references, nor would such review suggest the direction taken or even possible benefits addressed by Applicant as expected.

Dependent Claims 31-33

These claims were rejected, in addition to other specified theories, at least in part based upon similar allegations of the applicability of the combination of cited references to render as obvious Applicant's structurally co-deposited composite surface incorporating composite particles of bioerodible material and bioactive material into a coating material with conformed pores around the particles. Applicant similarly traverses this aspect of these grounds for rejecting these claims as applied for other claims above. Furthermore, these particular dependent claims further introduce still further limitations also not provided by either or both of the cited references in combination. In one particular regard, for example, Claim 33 requires a fourth material on the third material of the substrate be an electroplated metal, a fifth material on the fourth material be an electrolessly electrochemically deposited material with a metal and a reducing agent of the metal, and that the first porous material layer be constructed of another second electrolessly electrochemically co-deposited layer of metal, metal reducing agent, and further incorporating co-deposited composite particles of bioerodible and bioactive materials. Aside from the still prevailing absence of such composite bioerodible/bioactive particles, the other aspects of this specific combination of layers, in specific structural form and types of materials recited, are not found or suggested in Gertner as alleged in the Office Action. See also Applicant's disclosure at [00104].

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 20-28, 31-33, 45 and 46 under 35 USC § 103.

Claim 38 is rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 1, in view of Wang et al. (US 2007/0037739).

Regarding claim 38, the Office stated that although O'Brien et al. do not disclose the bioactive agent may comprise des-aspartate angiotensin 1 ("DAA-1", Wang et al. disclose compounds useful in coating stents to treat restenosis including des-asparate angiotensin 1 which has been shown to substantially inhibit smooth muscle cell proliferation and drastically reduce restenosis.

Applicant submits that O'Brien et al. in view of Wang et al. do not teach or suggest the elements of presently amended independent claim 2 and its dependent claims. More specifically, the combination of O'Brien et al. and Wang et al. do not teach or suggest the second composite material of the present endolumenal stent system comprising a **plurality of discrete particles, much less constructed of composite combination of bioerodible material and bioactive material, much less in a structurally co-deposited composite surface coating**.

Furthermore, Wang et al. had not presented any evidence or adequate description that DAA-1 can be placed into a coating environment with a result suitable to coat a stent, much less a co-deposition environment, as Applicant's disclosure has provided. Accordingly, Applicant asserts that Wang et al. does not adequately provide sufficient disclosure to place DAA-1 in a coating arrived at in combination with O'Brien, while that combination furthermore does not result in Applicant's claimed coating anyway.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claim 38 under 35 USC § 103.

Claims 40-42 are rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 1.

Regarding claims 40-42, the Office stated that although O'Brien et al. do not disclose the ratio of bioactive material to the bioerodable material it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the second composite material was formed

with a ratio of bioactive material to bioerodable material to be at least 0.5:1, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art.

Applicant submits that O'Brien et al. does not teach or suggest the elements of presently amended independent claim 2 and its dependent claims. More specifically, O'Brien et al. does not teach or suggest the second composite material of the present endolumenal stent system comprising a **plurality of particles, much less particles of composite construction with a bioerodible material in combination with a bioactive material, much less such particles in a structurally co-deposited composite surface coating.**

In view of the foregoing, Applicant respectfully request reconsideration and withdrawal of the rejection of claims 40-42 under 35 USC § 103.

CONCLUSION

Applicant has amended the present claims in order to clarify certain aspects previously presented prior to the present amendment, and which distinguish over the cited references alleged to provide grounds for rejection in the recent Office Action. All amendments made have been for clarity, and find abundant support in the present Application as originally filed, and no new matter has been added nor should any new search be required by this Amendment. The present amendments have been made in good faith in order to provide clarity to the originally intended subject matter of the claims prior to this amendment to expedite the application toward positive allowance. However, these amendments have been made without prejudice, estoppel, or dedication to the public of the original scope of the claims, as originally filed or otherwise in their intervening form prior to this Amendment, and reserves the right to pursue that subject matter prior to this amendment for future prosecution, such as for example via continuation practice.

Applicant has also provided remarks to accompany the present amendment, which include request for reconsideration and withdrawal of all grounds for rejection in the Office Action. All grounds for rejection being adequately addressed and traversed,

Applicant respectfully requests that a Notice of Allowance be issued and that the present Application please be passed to issuance.

Should the Examiner find any outstanding issue(s) remain which is/are require to be addressed prior to allowing the present Application, Applicant respectfully requests that the Examiner contact the undersigned Applicant's representative to give an opportunity to address such issue(s) in person prior to issuing a subsequent formal written action not constituting an Notice of Allowance.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

Dated: 12 January 2009

/Daniel S. Kim/
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